



PATENTZ-Z #21/D

In re Application of:

Paul M. Scopton

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09/498,104

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For:

FLUID INJECTABLE SINGLE OPERATOR EXCHANGE CATHETERS AND

METHODS OF USE

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AMENDMENT AFTER FINAL

TECHNOLOGY CENTER R3700

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certified that this paper or papers, as described herein are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of: EV 315612696 US, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of January 2004.

By <u>Kathleen Z. Bock</u> Kathleen L. Boekley

Dear Sir:

This paper is in response to the Final Office Action mailed November 24, 2003, with a priority response period set to expire January 24, 2004 and a shortened statutory period set to expire on February 24, 2004. This paper is filed within the set priority period for response such that no extension of time is necessary.

Please consider the following amendments and remarks:

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (previously submitted) A single operator exchange biliary catheter for use in combination with a guidewire and an endoscope, comprising:

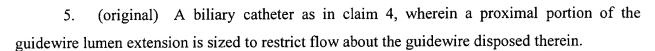
an elongate shaft having a proximal end, a distal end and an injection lumen extending therethrough;

a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft within the distal portion of the shaft, the distal guidewire port disposed at the distal end of the shaft;

a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen and adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein, the guidewire lumen extension being external to but parallel with the shaft; and

wherein the guidewire lumen extension is axially aligned with the guidewire lumen.

- 2. (original) A biliary catheter as in claim 1, wherein the tubular member has a distal end disposed distal of the proximal guidewire port.
- 3. (original) A biliary catheter as in claim 2, wherein the tubular member is disposed about the shaft.
- 4. (original) A biliary catheter as in claim 3, wherein the distal end of the tubular member is fluidly sealed about the shaft.



6. (cancelled)

- 7. (previously presented) A biliary catheter as in claim 1, wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port.
- 8. (original) A biliary catheter as in claim 1, wherein the tubular member has a length of approximately 5 to 30 cm.
- 9. (original) A biliary catheter as in claim 8, wherein the tubular member comprises a heat shrink tube.
- 10. (previously presented) A single operator exchange biliary balloon catheter for use in combination with a guidewire and an endoscope, comprising:

an elongate shaft having a proximal end, a distal end, an injection lumen and an inflation lumen extending therethrough;

an inflatable balloon disposed adjacent the distal end of the shaft in fluid communication with the inflation lumen;

a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft within the distal portion of the shaft, the distal guidewire port disposed at the distal end of the shaft; and

a tubular member disposed about the shaft, the tubular member having a proximal end disposed distal of the proximal end of the shaft, and a distal end disposed distal of the proximal guidewire port, the tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen and adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein, the guidewire extension lumen being external to

Appl. No. 09/498,104 Amdt. AF dated January 22, 2004 Reply to Final Office Action of November 24, 2003

but parallel with the shaft;

wherein the guidewire lumen extension is axially aligned with the guidewire lumen.

- 11. (original) A single operator exchange biliary balloon catheter as in claim 10, wherein the distal end of the tubular member is disposed adjacent the proximal guidewire port.
- 12. (original) A single operator exchange biliary balloon catheter as in claim 11, wherein the distal end of the tubular member is fluidly sealed about the shaft.
- 13. (original) A single operator exchange biliary balloon catheter as in claim 12, wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein.

14. (cancelled)

- 15. (previously presented) A single operator exchange biliary balloon catheter as in claim 10, wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port.
- 16. (original) A single operator exchange biliary balloon catheter as in claim 10, wherein the tubular member has a length of approximately 5 to 30 cm.
- 17. (original) A single operator exchange biliary balloon catheter as in claim 16, wherein the tubular member comprises a heat shrink tube.
 - 18. (withdrawn) A method of using a biliary catheter, comprising the steps of: providing an endoscope;

providing a guidewire;

providing a biliary catheter wherein the catheter includes an elongate shaft having a proximal end, a distal end and an injection lumen extending therethrough, a relatively short guidewire lumen extending through a distal portion of the shaft between a proximal guidewire

Appl. No. 09/498,104 Amdt. AF dated January 22, 2004 Reply to Final Office Action of November 24, 2003

port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, and a tubular member defining a guidewire lumen extension, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension;

inserting the endoscope into an alimentary canal of a patient;

inserting the guidewire into the guidewire lumen of the catheter;

inserting the catheter and guidewire into the endoscope;

retracting the guidewire from guidewire lumen such that a distal end of the guidewire resides in the guidewire lumen extension; and

injecting fluid into the lumen of the catheter, through the guidewire lumen and out the distal guidewire port.

- 19. (withdrawn) A method of using a biliary catheter 18, further comprising the step of: re-inserting the distal end of the guidewire into the guidewire lumen.
- 20. (withdrawn) A method of using a biliary catheter as in claim 19, wherein the biliary catheter includes an inflatable balloon further comprising the step of:

inflating the balloon.